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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/770,241 | 02/02/2004 | James A. Laugharn JR. | 07985-031002 | 9463 |

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BOSTON, MA 02110

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| EXAMINER |
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MCKANE, ELIZABETH L

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| ART UNIT | PAPER NUMBER |
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1744

DATE MAILED: 01/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/770,241

Applicant(s)

LAUGHARN ET AL.

Examiner

Leigh McKane

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-31 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 020204.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-3, 6, 7, 13, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Hashizume et al ("Kinetic Analysis of Yeast Inactivation by High Pressure Treatment at Low Temperatures").

3. Hashizume et al teaches a method for sterilizing a foodstuff material (which contains desired biomolecules such as nutrients, proteins, carbohydrates, etc.) wherein the material is provided at ambient conditions, exposed to an elevated pressure of 120 and 300 MPA (17400 and 43500 psi), and the pressure released. Since the pressure of Hashizume et al is within the range claimed, it is insufficient to irreversibly denature proteins. The material is preferably at a temperature of -20° to 50°C before pressurization. See page 1455. The material of Hashizume et al is initially contaminated with yeast (fungus).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 4, 5, 11, 12, 15-17, 21, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hashizume et al.

With respect to claims 4 and 5, the Temperature-Pressure Diagram in Figure 4 of Hashizume et al illustrates that pressure inactivation improves as the temperature either drops below -20°C or rises above 40°C . Thus, it would have been obvious to one of ordinary skill in the art to optimize the temperature of Hashizume et al for improved pressure inactivation.

As to claims 11, 12, 21, and 22, since Hashizume et al discloses treating the material at a temperature from -20° to 50°C , it would have been obvious to bring it to this temperature by warming if the material is initially in a deep frozen state. Similarly, when the product must be first cooled before treatment in order to bring it within the necessary temperature range, it would have been obvious to warm it after treatment, to bring it back up to its original temperature.

With respect to claims 15-17, Hashizume et al teaches a method for sterilizing a foodstuff material wherein the material is provided at ambient conditions, exposed to an elevated pressure of 120 and 300 MPA (17400 and 43500 psi), and the pressure released. The material is preferably at a temperature of -20° to 50°C before pressurization. See page 1455. The material of Hashizume et al is initially contaminated with yeast (fungus). Regardless, Hashizume et al teaches that “[h]igh hydrostatic pressure inactivates microorganisms” and goes on to disclose the known inactivation of spores, some *bacillus* species, and *E. coli* using hydrostatic pressure. Thus, it would have been obvious to one of ordinary skill in the art to employ the method of Hashizume et al to sterilize material containing microorganisms other than yeast.

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6. Claims 8-10 and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hashizume et al as applied to claims 1 and 15 above, and further in view of Hayakawa et al ("Oscillatory Compared with Continuous High Pressure Sterilization on *Bacillus stearothermophilus* Spores").

Hashizume et al teaches substantially the method claimed but discloses a continuous application of high pressure upon the sample and does not disclose repeatedly cycling the pressure. However, this concept is evidenced by Hayakawa et al, who discloses that oscillatory (cyclic) pressurization is more effective than continuous pressurization in sterilizing spores. See Abstract. Since Hashizume et al envisions use of the high pressure treatment on all types of microorganisms, not just yeasts, it would have been obvious to use the cyclic pressurization of Hayakawa et al in the method of Hashizume et al. Moreover, it would have been obvious to optimize the number of cycles and the pressure differential, as such is readily determinable through routine experimentation.

7. Claims 24-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hayakawa et al in view of Hashizume et al.

Hayakawa et al teaches sterilization of food contaminated with bacterium spores by cyclic pressurization but does not teach doing so at a temperature below about 40 °C. See Abstract. Hashizume et al discloses pressurization at sub-zero temperatures and teaches that "pressure sterilization conditions can be improved further when sterilization is done at low temperatures including sub-zero temperatures" (page 1457, last line of column 2). Therefore, it would have been obvious to use lower temperatures in the method of Hayakawa et al.

As to warming or cooling the material, since Hashizume et al discloses treating the material at a temperature from -20° to 50°C , it would have been obvious to bring it to this temperature by warming if the material is initially in a deep frozen state. Similarly, when the product must be first cooled before treatment in order to bring it within the necessary temperature range, it would have been obvious to warm it after treatment, to bring it back up to its original temperature.

Conclusion

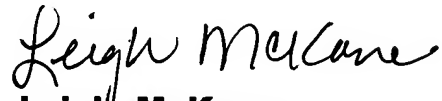
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh McKane whose telephone number is 571-272-1275. The examiner can normally be reached on Monday-Wednesday (7:15 am-4:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 571-272-1275. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Leigh McKane

Primary Examiner

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3 January 2005